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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,451	01/27/2004	Craig A. Townsend	62732.000152	8691

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
EPPERSON, JON D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,451	TOWNSEND ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-48* is/are pending in the application.

4a) Of the above claim(s) *25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on February 3, 2005.

Status of the Claims

2. Claims 25-48 are pending.

3. Applicant's response to the Restriction and/or Election of Species requirements is acknowledged (Applicant elected ***with traverse*** Group IV, claims 30-48 (in part)) and claims 25-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see ***Response to Restriction and/or Election of Species*** below wherein Groups V and VI are joined with Group IV as requested by Applicants).

4. Therefore, claims 30-48 are examined on the merits in this action.

Response to Restriction and/or Election of Species

5. Applicant's election of Group I (claims 30-48 (in part)) **with traverse** is acknowledged.

6. The traversal is on the ground(s) that "... it would not constitute a burden to examine the inventions of Groups IV-VI together. The inventions ... analogous to

Groups IV-VI were recombined and examined together [in the parent application]" (e.g., see 2/3/05 Response pages 4-5).

7. The Examiner finds Applicants' arguments persuasive and, as a result, the restriction requirement with regard to Groups IV-VI is hereby withdrawn as requested. In addition, the restriction requirement with regard to Groups I-III is also withdrawn. Thus, only two groups (i.e., Group I drawn to the compounds and Group II drawn to the method for treating an animal using said compounds remain).

8. With regard to the species election, Applicants argue that it would not constitute an undue burden to the examiner to examine all the species in the Subgroups together because the species are "closely related to each other" by subject matter (e.g., see 2/3/05 Response, page 6).

9. The Examiner agrees with Applicants and hereby withdraws the species election.

10. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

11. The information disclosure statement filed June 1, 2004, fails, in part, to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because publications cited therein, numbered 26, lack publication dates, a necessary element for consideration.

While the other patent and other publications cited therein, and supplied, therewith, have been considered as to the merits, these three publications have not. Applicant is advised that the date of any re-submission of these citations contained in this information disclosure statement or the submission of the missing element – their publication dates – will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPE § 609 C(1).

12. The listing of references in the specification (and attachments in the 6/1/04 IDS used as PTO-892 form in a previous application or as PTO-892 forms that were submitted in previous applications) is/are not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

13. The references listed on applicant's PTO-1449 form have been considered by the Examiner. A copy of the form is attached to this Office Action (e.g., 6/1/04 IDS).

Specification

14. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 30-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the claimed compounds wherein Z is -CH_2- or -CH=CH- to inhibit a narrow range of mycobacterium including *tuberculosis*, *bovis* and *avium-intracellulare*, does not reasonably provide enablement for the treatment of "any" microbial-based infections using the full scope of the claimed compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". Some of these factors may include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are broad because they include the treatment of "any" microbial-based infection, which would encompass a large number of unrelated etiologies. In addition, the scope of the claims includes many compounds that are not sufficiently related in structure to the prototypical β-ketoacyl synthase "transition state" inhibitors presented to be of medicinal use (i.e., many of the claimed compounds are missing "essential" elements, see below). Consequently, the nature of the invention cannot be fully determined because the invention has not been defined with particularity.

(3 and 5) The state of the prior art and the level of predictability in the art: The prior art indicates that Applicants' claimed compounds can only be used to treat a very narrow range of mycobacterial species including *tuberculosis*, *bovis* and *avium-intracellulare* (e.g., see Jones, P. B.; Parrish, N. M.; Houston, T. A.; Stapon, A.; Bansal, N. P.; Dick J. D.; Townsend, C. A. "A New Class of Antituberculosis Agents" *J. Med. Chem.* **2000**, *43*, 3304-3314, page 3308, column 1, last full paragraph, "The compounds marked with an asterisk in Table 1 [i.e., Applicants' claimed compounds] were also tested against other bacterial strains

including *Staphylococcus aureus* (ATC 29213), *Enterococcus faecalis* (ATCC 29212), *Escherichia coli* (ATCC 25922), and *Pseudomonas aeruginosa* (ATCC 27853). ***None exhibited any activity against these bacteria***"; see also page 3309, column 1, paragraph 1, "... these compounds are highly species-specific [i.e., Applicants' claimed compounds], whosing no activity against other bacteria including strains of nonpathogentic mycobacteria, such as *M. smegmatis* [i.e., no activity even for other closely related mycobacteria"; see also Table 1 in specification).

In addition, the Jones et al. indicate that these compounds function as β-ketoacyl synthase "transition state" inhibitors (e.g., see Jones et al., page 3305, shaded region in scheme 1) and thus require certain "essential" structural features (e.g., see Jones et al., page 3306, column 1, paragraph 1, "Compounds in this family consist of four [essential] structural elements. These are an acyl derivative, spacer, tetrahedral mimic and hydrophobic tail"). In addition, Jones et al. disclose that the "spacer" element must consist of only a methylene unit (e.g., see Jones et al., page 3306, column 1, last paragraph, "Most of the compounds shown in Table 1, and all active compounds, have a single methylene spacer between the tetrahedral mimic and acyl center. The exceptions, 12, 13, and 28-30, are inactive").

(4) The level of one of ordinary skill: The level of skill required would be high, most likely at the Ph.D. level.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants provide only a narrow ranges of examples where

their claimed compounds are used to treat *tuberculosis*, *bovis* and *avium-intracellulare*. In addition, Applicants' specification does not contradict in any way the assertion that the "spacer" element must be a methylene group, with the exception of the -CH=CH- group noted above (e.g., see specification, Table 1).

(8) The quantity of experimentation needed to make or use the invention base on the content of the disclosure: As a result of the broad and unpredictable nature of the invention and the lack of specific guidance from the specification, the Examiner contends that the quantity of experimentation needed to make and or use the invention would be great. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 * n.23 (Fed. Cir. 19991). In this case, Applicants have not provided any working examples that would teach this enormous genus that falls within a highly unpredictable art area. Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
May 16, 2005